novacare

ASX Digital

Operating instructions

Pressure sore prevention
Alternating pressure

With the ***nova*care® ASX digital alternating pressure system,** you have acquired a Pressure sore prevention system..

A good decision
Your novacare® – Team

Please read the following operating instructions carefully commissioning the system.

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1. The System:

Consists of a high-quality control unit with a membrane pump and a mattress replacement with 18 air cells arranged in a transverse manner and a base mattress. The mattress replacement system is additionally equipped with a high-quality, bi-elastic, steam-permeable, water tight wraparound protective cover.

2. Scope of supply:

- Alternating pressure system **ASX digital**
- Alternating pressure mattress replacement
- Carry bag
- Operating instructions

3. Indication / Contraindication:

Indication :	Treatment and prevention of pressure ulcers and decubitus
Contraindication :	alternating pressure should not be used for patients in pain or patients with a low pain threshold. Use the device in the static mode for such patients.

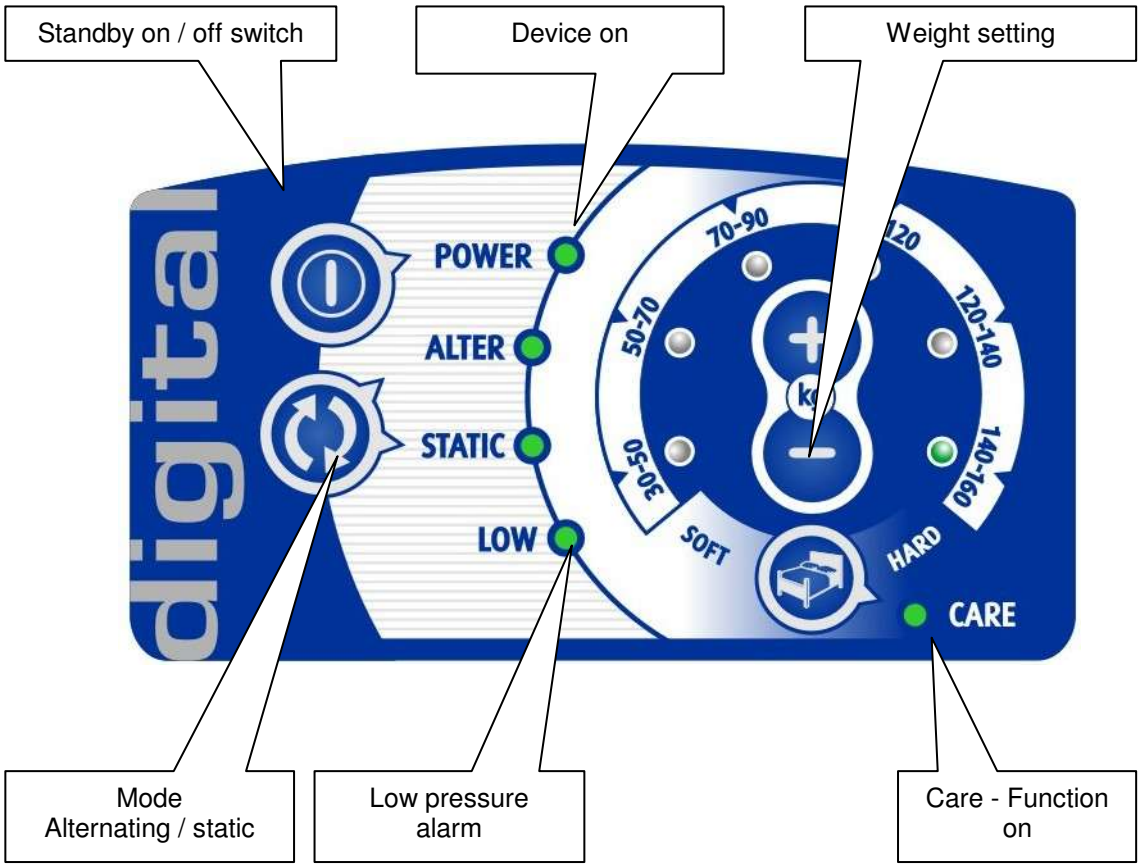
4. Severity of Decubitus / Area of application :

The **novacare® Alternating pressure system ASX digital** is recommended for Decubitus up to Grade IV (very high risk).

5. Maximum load / Patient weight

The **novacare® Alternating pressure system ASX digital** has been designed for a maximum patient weight of **185 kg**.

6. Operating elements/ Controls/ Key layout / LED-Displays :



7. *Preparing the system for commissioning :*

1. First, remove the existing mattress on the bed of the patient. Now, take the entire mattress system from the carton and keep it on the grid of the bed of the patient.
2. Remove the control unit from the carton and attach it to the foot end of the bed with fixing hooks.

   The foldable clamps proved a secure hold of the system to the foot of the bed. Please ensure that the connecting tube is located at the foot end of the bed.
3. Unroll the base mattress if necessary and insert inside a separate pocket below the cell chambers.
4. Fix the complete mattress overlay with 6 fastening belts to the slatted frame.
5. Now, connect the Plug of the mattress in-feed tube (remove the transport lock beforehand) with the connector to the underside of the control unit. Please ensure that the plug is engaged properly.
6. Insert the power plug into a 220 V socket.
7. Start the pump by pressing the standby button for about 2 secounds.

8. Now, depending upon the desired operating mode, set the unit using the mode key to alternating mode (LED – Display “ALTER“ glows) or the static mode (LED – Display “STATIC“ glows)
9. The process of inflation takes approx. 20-25 minutes.
10. Please now adjust the pressure / weight setting according the patient weight (recommendation only, please observe topic 8)-
11. The system is ready to be operated, if the display ’LOW’ (see alarm functions) disappears.

Attention :

When raising the head rest portion of the bed please increase mattress pressure by 1 to 2 settings

8. Setting of patient weight:

Please check the numbers on the dial when setting the best suitable patient cell pressure.

Please consider that these pre-settings are recommendations only. Please conduct the „Practical Test“ in any case and make individual adjustments until you determine the correct setting for the patient in question.

9. Static mode:

The unit can be operated in static mode for special applications (for example pain patients, patient transport). In static mode all cells are ventilated with the same pressure, the alternating effect is stopped. Please note that due to the cyclic adjustment of the drive the switching to static mode may take a few minutes.

We recommend to set the pressure to 1-2 settings lower than indicated on the dial scale. Conduct a system check as well.

LED lights up immediately after static mode has been initiated. Static mode adjusts automatically inside the drive cycle.

10. Alarm function:

The ***nova*****care® ASX digital Alternating pressure system** features an alarm system. It visually and acoustically displays low pressure failure.

Upon commissioning, the system is in low pressure during the inflation phase up until it has been completely vented. The optical low pressure indicator „LOW“ lights up. The acoustic alarm features a delay function, which considers the duration of inflation. The alarm automatically activates after about 45 minutes.

If, for example, during re-positioning the pressure sinks below 20 mm/Hg for a short time, the acoustical alarm changes to a 5 minute delay. If there is still low pressure after this delay, the alarm is activated.

This avoids a disturbing, undesired alarm.

11. Using the Care-Function

The control unit of **ASX digital** is equipped with a CARE function. On activating this function, all chambers of the mattress system are filled with maximum system pressure for 30 minutes. After 30 minutes, the system automatically switches over to the alternating pressure mode for the safety of the patient.

This function simplifies the process of shifting patients from one location to another during treatment.

12. Practical Test:

In case of optimum and correct pressure, you should be able to pass your hand between the patient and an inflated cell without any difficulty.

13. System operation with one cell extracted:

Operating the system with a cell removed requires an additional adapter which is not included in the scope of supply. It is a coupling which replaces the T-tube connector. (Optional, item no. 991015).

1. Remove the cell in question (except head cells).
2. Now remove the T piece which connects the main tube to the cell.
3. Now connect the main tube to the coupling, item no. 991015.
4. Now the system can commence operations in the above mentioned sequence.

14. Alternative positioning of the control unit:

The control unit of **ASX digital** can also be operated in a horizontal position, if a suspension is not desirable or not possible at the head end. Legs provided for the control unit enable secure positioning and provide adequate gap for air circulation. In any case, see to it that there is proper air circulation and that the air filter is not blocked (e.g. in case of floors with thick carpets).

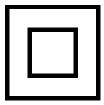
15. Transportation of patients / operation without power

In case of separation from power supply (i.e. patient transportation) pressure within the alternating pressure mattress can be maintained for a certain amount of time. Two options apply. First switch the system to static mode.

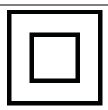
a) Pull the power plug. System pressure is maintained for 15-20 minutes and is then gradually reduced.
b) Separate the control unit from the alternating pressure mattress. Release and remove the Trio plug at the control unit. Put the cap onto the socket and ensure that the it catches properly. This has to be done quickly in order to avoid loss of pressure. The system maintains the pressure for several hours. We recommend to check the overlay for sufficient pressure in regular intervals.

16. Technical data :

- control unit : weight 2.5 kg
  dimensions : 30 x 22 x 12 cm
  length power cord 3.8 m
  rated speed : AC 220-240 V / 50 Hz
  Max. 0.2 A
  Fuse rating : TIAH 250 VAC 1A
  protection class : Type BF / Class II
- Mattress : weight : 11,8 kg
  dims (w/o base) : 200 x 90 x 18 cm
  material (cover) PU
- cells : dims : 90 X 15 cm
  material Nylon, PU-coated
- Max. infl .pressure w/o weight 75 – 85 mm Hg
- Min. infl. pressure w/o weight 20 mm Hg
- cycle 10 min.
- surrounding conditions:
  Rel. Air humidity 20 % – 90 %
  Temperature operation 15° ~ 35°C
  Storage -10°~ 65°C



Symbol Definition

	Class II Equipment
	Ref Refer to Accompanying Documents
	Waste Disposal
	Type BF Applied Part
	Alternating Current
	Warning

17. Technical safety:

- Testing according to DIN EN 60601-1-2:2006
- Testing according to DIN EN 60601-1:2005
- Testing according to DIN EN 60000-3-2:1995
- Testing according to DIN EN 60000-3-3:1995
- Fire test to DIN EN 597/1 and DIN EN 597/2 (Cell)
- California – Firetest Class I (Cover)
- 1 Membrane compressor
- Tension relief of the power cable
- Splash-proof
- Alarm function
  - Low pressure alarm, optical & accoustic
- CPR-Emergency valve

18. Practical Testing for toxicological harmlessness and biocompatibility (compliance of standards)

- DIN EN ISO 10993-1:1998
- ASTM F 813

19. CPR - Valve :

novacare® alternating pressure system **ASX digital is** equipped with a CPR emercency valve It facilitates an quick deflation within seconds, for example to conduct a resuscitation. In this case set the valve to switch position „open“.

20. Warning / ⚠ Caution :

Warning

- Connect the Master Control unit to a proper power source.
- Don’t use the system in the presence of any flammable gases. (such as Anesthetic Agents)
- Keep the pump and mattress away from source of liquid of open flame.
- Keep the mattress away from sharp object.
- The device is not AP/APG protected.
- Don’t place the heating device close to the mattress system.

⚠ Caution

- Protect the control unit from humidity and direct wetness
- Use the mattress under the physician’s instruction
- Keep the tubes free of bends
- Re-positioning the patient in certain period of time is still necessary when using this system
- Do not use the system in the proximity of a source of heat

- Pull out the power plug while moving the bed.
- Never pull the cable.
- Sharp objects must be kept away. Do not fix the overlay with inappropriate means.
- Do not use the system in the proximity of inflammable gases (risk of explosion)
- Use only genuine spare parts and consumables
- The Control unit can only be repaired by authorized distributor.
  (The circuit diagram, repairable component parts list, and service manual are released only to authorized distributor)
- Don't drop the control unit
- Do not store the system in direct sunlight or extreme cold conditions

21. Maintenance / Inspection

The ***nova*care® alternating pressure system ASX digital** is considered to be a medical device according to RL 93/42 and MPG. Follow these statutory regulations while using the device.

Maintenance at regular intervals is necessary to preserve the function of ***nova*care® Alternating pressure system ASX digital**. This must be undertaken latest after 24 months from the date of purchase.

Maintenance / inspection is conducted by the manufacturer or by his authorized contractor at a charge.

If maintenance / inspection is not conducted at all or is conducted not as per schedule or not by an authorized agency, then the warranty and warranty claims are no longer valid. Damages or any other loss of function arising from lack of maintenance or untimely maintenance / inspection or interference by an unauthorized agency likewise leads to loss of warranty and warranty claims (see Warranty)

The following measures are to be implemented during maintenance / inspection:

- Replace the membrane unit
- Replace the air filter
- Replace the synchronous motor (every second service)
- Conduct function test / function inspection
- Sealing of the case and attaching an inspection sticker

Maintenance / inspection undertaken by the Service department of novacare gmbh is recorded and documented.

22. Hygiene

Systems designed for reuse must be prepared on the basis of locally valid directive, laws or regulations "for Hospital hygiene and Infection prevention".

Already validated procedures and hygiene schedules, if any, must be applied for this preparation.

Please act according to your locally valid hygiene directives and the respective list of disinfectants for disinfecting the products and use only disinfectants listed in them. Follow the instructions for use prescribed by the respective manufacturer.

Warranty claims become null and void if inappropriate and unlisted preparations are used or are used inappropriately.

We recommend our cleaning service. Please inquire about the applicable charges.

23. Care, cleaning, disinfection

The *nova*care® ASX digital alternating pressure system wraparound protective cover can be cleaned chemical-thermally by machine up to 60°. For disinfection we recommend the use of an approved disinfection cleaning additive. To increase the life span clean cells by spray/wipe disinfection. In special cases chemical-thermal cleaning is possible as well.

Please ensure that the cell body opening are shut when cleaned by machine.

For use, follow the recommentions of the respective manufacturer.

This measure might not replace hygiene regulations currently valid in your country and should be applied only in special cases (i.e. interim cleaning of acute contamination).

- Waste Disposal :

This Product has been supplied from an environmentally aware manufacturer that complies with the WEEE.
This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according the legislation. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.

24. EMC Table :

Guidance and manufacturer's declaration – electromagnetic emissions		
The Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	□6 kV contact □8 kV air	□6 kV contact □8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	□2 kV for power supply lines □1 kV for input/output lines	□2 kV for power supply lines □1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	□1 kV line(s) to line(s) □2 kV line(s) to earth	□1 kV line(s) to line(s) □2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Equipment] requires continued operation during power mains interruptions, it is recommended that the Equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Equipment is used exceeds the applicable RF compliance level above, the Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Equipment. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Equipment			
The Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Equipment as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

25. Warranty :

- The warranty is based on statutory regulations.
- Every warranty is excluded immediately, if the goods supplied by us are processed, handled or modified by other parties without our consent or if our operating instructions are not followed. If the seals are damaged, it will be assumed that the aforesaid activities have been carried out.
- For medical devices as understood by the EG-Directive 93/42/EEC, whose usage is subject to regular service and maintenance, a warranty can be offered only if the service intervals prescribed by the manufacturer are adhered to.
- As far as warranty claims are accepted and if during the subsequent inspection it is found that the damages are of wear and tear or are not subject to warranty, then we are empowered to claim the expenses (inspection, transport costs etc.) from the customer.
- The use of parts or individual components of other systems or products or combinations thereof are not permissible. Warranty claims cease to exist for any damage resulting from this, which must be borne by the user

26. Designation / Article-No. :

- Article No.: **997108 UK**

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